MAR 3 0 2010

5. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.
The assigned 510(k) number is: K091313.

1. Submitted by:	Sysmex America, Inc. One Nelson C. White Parkway Mundelein, IL. 60060 Phone: (847) 996-4618; FAX: (847) 996-4655 Contact person: Sharita Brooks Date prepared: April 30, 2009
2. Name of Device:	Trade or proprietary name: Sysmex® XT-4000*i* Common name: Automated Hematology Analyzer Classification name: Automated Differential Cell Counter 21 CFR 864.5220
3. Predicate Device:	Sysmex® XT-Series Sysmex® XE-5000, Body Fluid Mode
4. Device Description:	The XT-4000*i* is the same as the XT-2000*i* which is part of the XT-Series and has a Body Fluid mode the same as the XE-5000. It is an automated hematology analyzer which consists of four principle units: (1) Main Unit which aspirates, dilutes, mixes, and analyzes whole blood and body fluid samples; (2) Sampler Unit which supplies samples to the Main Unit automatically; (3) IPU (Information Processing Unit) which processes data from the Main Unit and provides the operator interface with the system; (4) Pneumatic Unit which supplies pressure and vacuum from the Main Unit. The Body Fluid analysis mode of the XT-4000*i* uses the 4DIFF scattergram & the RBC distribution obtained from a specialized analysis sequence to calculate & display the WBC (WBC-BF) counts, mononuclear cell (MN) / polymorphonuclear cell (PMN) counts & percentages, TC-BF (Total Count) & RBC (RBC-BF) counts found in the body fluid.
5. Intended Use:	The Sysmex® XT-4000*i* is a quantitative multi-parameter automated hematology analyzer intended for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XT-4000*i* classifies and enumerates the following parameters for whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, RET%/#, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/# and TC-BF# parameters in cerebrospinal fluids (CSF), serous fluids (peritoneal, pleural) and synovial fluids. Serous and Synovial fluids should be collected in K_2EDTA to prevent clotting of fluid. The use of anticoagulants with CSF specimens is not required or recommended.
6. Substantial equivalence-similarities and differences	The following table compares the XT-4000*i* with the XT-Series and the XE-5000 Body Fluid Mode.
7. Clinical Performance Data:	Studies were performed to evaluate the equivalency of the XT-4000*i* to the XE-5000 Body Fluid Mode. Results indicated equivalent performance.
8. Conclusions:	The performance data demonstrated substantial equivalence.

Table 1: Substantial Equivalence – Similarities and Differences to the XT-Series and XE-5000 Body Fluid mode

Features (Submission #)	XT-4000*i*	XT-Series (K021241)	XE-5000 (K071967)
FDA Clearance	---	25-June-02	20-Nov-07
Intended Use	The Sysmex® XT-4000*i* is a quantitative multi-parameter automated hematology analyzer intended for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XT-4000*i* classifies and enumerates the following parameters for whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, RET%/#, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/# and TC-BF# parameters in cerebrospinal fluids (CSF), serous fluids (peritoneal, pleural) and synovial fluids. Serous and Synovial fluids should be collected in K_2EDTA to prevent clotting of fluid. The use of anticoagulants with CSF specimens is not required or recommended.	The Sysmex® XT-2000*i* is intended for *in vitro* diagnostic use in the clinical laboratory as a multi-parameter hematology analyzer. The XT-2000*i* has a Body Fluid Application which adds a quantitative, automated procedure for analyzing body fluids (cerebrospinal fluids (CSF), serous fluids, and synovial fluids with EDTA, as needed) to the XT-2000i, providing enumeration of the WBCs and the RBCs.	The Sysmex® XE-5000 is an automated hematology analyzer for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XE-5000 has a Body Fluid mode for body fluids. The Body Fluid mode analyzes WBC-BF, RBC-BF, MN%/#, PMN%/# and TC-BF in body fluids (cerebrospinal fluids (CSF), serous fluids, and synovial fluids with EDTA, as needed).
Sample Type	Whole blood/ Body Fluids	Whole blood/Body Fluids	Whole blood/Body Fluids
Parameters	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, RDW-CV, RDW-SD, MPV, RET%/#, IRF, IG%/#, RET-He# **Body Fluid Mode**: WBC-BF, RBC-BF, MN%/#, PMN%/#, TC-	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, RDW-CV, RDW-SD, MPV, RET%/#, IRF, IG%/#, RET-He#. **Body Fluid Application**: WBC-BF, RBC-BF	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, NRBC%/#,RDW-CV, RDW-SD, MPV, RET%/#, IRF, IG%/#, HPC#, RET-He#, IPF. **Body Fluid Mode**: WBC-BF, RBC-BF, MN%/#, PMN%/#,TC-

	BF#		BF#
Reagents	CELLPACK™ (Diluent) STROMATOLYSER-FB™ (Lyse) STROMATOLYSER-4DL™ (Lyse) STROMATOLYSER-4DS™ (Stain) SULFOLYSER (Lyse) RET-SEARCH II (Diluent) RET-SEARCH II (Stain)	CELLPACK™ (Diluent) STROMATOLYSER-FB™ (Lyse) STROMATOLYSER-4DL™ (Lyse) STROMATOLYSER-4DS™ (Stain) SULFOLYSER (Lyse) RET-SEARCH II (Diluent) RET-SEARCH II (Stain)	CELLPACK™ (Diluent) CELLSHEATH™ (Diluent) STROMATOLYSER-FB™ (Lyse) STROMATOLYSER-4DL™ (Lyse) STROMATOLYSER-4DS™ (Stain) STROMATOLYSER-NR™ (Diluent) STROMATOLYSER-NR™ (Stain) STROMATOLYSER-IM™ (Lyse) SULFOLYSER (Lyse) RET-SEARCH II (Diluent) RET-SEARCH II (Stain)
Principles	Performs hematology analyses according to the Hydro Dynamic Focusing (DC Detection), flow cytometry method (using a semiconductor laser), and SLS-hemoglobin method.	Performs hematology analyses according to the Hydro Dynamic Focusing (DC Detection), flow cytometry method (using a semiconductor laser), and SLS-hemoglobin method.	Performs hematology analysis according to the RF/DC detection method, Hydro Dynamic Focusing (DC Detection), flow cytometry method (using a semiconductor laser), and SLS-hemoglobin method.
Dimensions (HxWxD) (mm)	630x520x720	630x520x720	711x706x535
Weight (kg)	59	59	81
Quality Control/ Calibrator	e-Check (XE) – 3 Levels Calibrator (X Cal)	e-Check – 3 Levels Calibrator (X Cal)	e-Check (XE) – 3 Levels XE Calibrator (X Cal)
Software/ Hardware Differences	The XT-4000*i* performs the same as the XT-2000*i* and **has a Body Fluid mode** the same as the XE-5000.	The XT-2000*i* **does not have a Body Fluid mode.** The XT-2000*i* has a Body Fluid Application.	The XE-5000 **has a Body Fluid mode.**
Throughput	Approx 80-100/hr Depending on mode used.	Approx 80 Depending on mode used.	Approximately 113-150 depending on mode used.
Equivalency Data	Data consisting of Accuracy, Precision, Linearity and Carryover was collected to show performance to the manufacturer's specification for the Body Fluid mode. This analysis supports the claim that the XT-4000*i* Body Fluid mode is substantially equivalent to the XE-5000 Body Fluid mode.	Proven performance in FDA submission	Proven performance in FDA submission

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center-WO66-G609
Silver Spring, MD 20993-0002

Sysmex America, Inc.
c/o Ms. Sharita Brooks, BBA, MT
Clinical Affairs Specialist
One Nelson C. White Parkway
Mundelein, IL 60060

MAR 3 0 2010

Re: k091313
Trade/Device Name: Sysmex XT-4000i
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: March 18, 2010
Received: March 19, 2010

Dear Ms. Brooks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known) K091313

Device Name: XT-4000*i*, Automated Hematology Analyzer

Indications for Use:

The Sysmex® XT-4000*i* is a quantitative multi-parameter automated hematology analyzer intended for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XT-4000*i* classifies and enumerates the following parameters for whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, RET%/#, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/# and TC-BF# parameters in cerebrospinal fluids (CSF), serous fluids (peritoneal, pleural) and synovial fluids. Serous and Synovial fluids should be collected in K_2EDTA to prevent clotting of fluid. The use of anticoagulants with CSF specimens is not required or recommended.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K091313